

## Corporate Overview

Manufacturers of Premium Pharmaceutical Ingredients and Bulk cGMP Fine Chemicals

Revision 9.7 09/18/2023

## Corporate Vision, Mission, Values

#### People Matter



#### **Vision**

Committed to be a **leading manufacturer** of pharmaceutical ingredients that support **safe** drugs and vaccines that deliver **consistent, reliable therapeutic effect** with every dose





To manufacture the highest quality, safest and sustainable Pharmaceutical ingredients under the supervision of the most rigorous quality system while upholding the most stringent compliance standards



## Values Henesty / Integrity / Pospect / S



Honesty / Integrity / Respect / Safety / Sustainability
BioSpectra rigorously upholds uncompromised standards
because... "people matter"

## Corporate Profile

BIOSPECTRA™ is a family of companies under common (private) ownership that incudes Dextran Products (Ontario, Canada), BioDevelopment Inc. (Rensselaer, NY) and BioSpectra Inc., located in Stroudsburg, Bangor and Wind Gap, PA, USA.

In addition to these seven manufacturing and storage facilities in North America, BioSpectra Inc. oversees contract R&D facilities in Mumbai, India and a cGMP manufacturing plant in Sarigam, India as well as several manufacturing sites in China for chemical raw materials. All Finished Products are fully tested and packaged under cGMP conditions if not purified and/or synthesized in the US.

As a true, global organization with US based manufacturing, packaging and testing of all its products, BioSpectra Inc. offers a unique range of products to the Pharmaceutical industry that includes Actives, Excipients, GMP Process Chemicals & Bulk GMP Buffers and Solutions

Our focus is small molecule synthesis and true, phase change multistep purification for both traditional and bio-pharmaceutical applications, coupled with robust Supply Chain Security and Sustainability programs.





## Corporate Profile

Our services include Contract GMP product development coupled with ongoing commercial manufacturing and regulatory support up to and including DMF submissions.

All our manufacturing processes are fully validated. Our cGMP Quality System & regulatory support package complies with USFDA, IPEC & ICHQ7 guidelines. Our onsite analytical testing capabilities include multi-compendial and custom specifications with full traceability and transparency of all raw materials and sources.

Our commitment is to quality, compliance and true, cGMP manufacturing with unparalleled regulatory & technical support, operating under the most rigorous quality system while holding to the most stringent regulatory demands.

Our goal is to be a valued partner in the secure supply chain and the solution to key ingredient issues our customers may have.

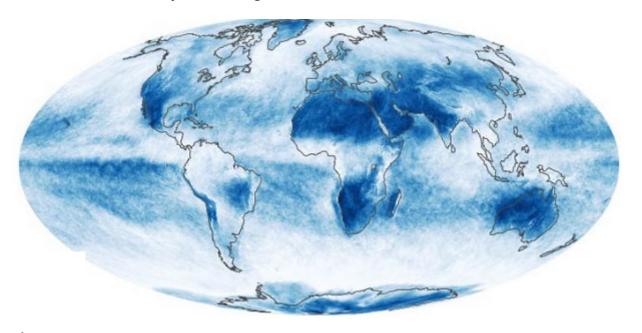




## Sustainability and Supply Chain Security

#### **Sustainability**

BioSpectra is committed to the ideals of Sustainability and has launched a three-year thirty million dollar capital investment program to help achieve these goals. We are currently working on an external program that is available on our website. We are registered with ECOVADIS, currently achieving Bronze Status.



#### **Supply Chain Security**

BioSpectra is fundamentally committed to the ideals of Supply Chain Security. We prosecute an aggressive raw material supplier qualification program. Our Quality Program is posted and available on our website. We take very seriously the global supply-chain situation assessing and reacting to threats with real solutions. BioSpectra Inc, continues it's long history of sourcing and qualifying raw material so as not to be sole sourced on any key chemical that originates from only one country.

#### Corporate Commitment to True GMP Products

- Authentic, Secure Supply Chain 100% Traceable Raw
   Materials from Qualified Sources
- Reliable, Consistent, Uniform, Quality-Based Manufacturing of Premium Ingredients
- Fully Validated GMP Manufacturing Systems & Qualified Equipment
- True GMP Product Claim Always Synthesized and/or Purified
- Manufactured Exclusively in the USA





#### **TRUE GMP**

BSI does not simply test and package under a "GMP system"; rather, we always increase the quality and compliance levels through multiple steps of synthetic manufacturing and/or purification for all BioSpectra labeled products.

#### PREMIUM PHARMACEUTICAL INGREDIENTS

#### MANUFACTURED EXCLUSIVELY IN THE USA

#### **GMP Product Categories**

- GMP Process Chemicals
- Bulk Custom Solutions
- Bulk Biological Buffers
- Functional Excipients
- Active Ingredients

#### **GMP Custom Services**

- GMP Product Development
- Small Molecule Synthesis
- Purification of Excipients
- Scale-Up, Bench to Bulk
- Regulatory (product) Support

#### **Corporate Values & Commitments**

- True GMP Product Claim-Always Synthesized and/or Purified, and not simply tested and repackaged
- Reliable, Consistent, Uniform, Quality-Based
- Authentic, Secure Supply Chains 100% Traceable Raw Materials from Qualified Sources
- Fully Validated GMP Mfg. Systems & Qualified Equipment

#### **Comprehensive Quality & Regulatory System**

- FDA Registered & Inspected
- Full Transparency in Documentation
- Stringent Quality Program & Controls
- Document Support- DMF Submissions
- Rigorous compliance to Global Standards
- FDA & ICH Q7 Guidance for Drug Substances
- State-of-the-art Instrumentation & Laboratories
- Culture of Embracing Evolving Regulatory Demands







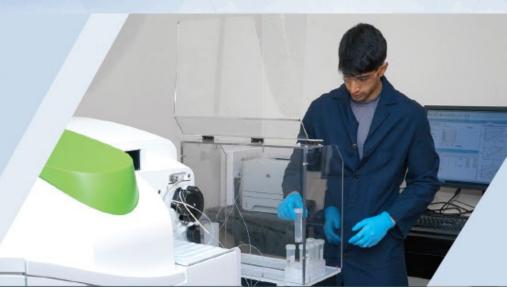




### Comprehensive Quality & Regulatory Program

#### Operating a Stringent Quality & Regulatory Program

- Upholding Global Regulatory Requirements
- Testing to the Highest Quality Standards
- Applying Rigorous Oversight & Controls



- Global GMP Standards Meeting US-FDA, ICH Q7 & IPEC Guidelines
- Comprehensive Internal Auditing of all Manufacturing Processes
- Regulatory Services including Drug Master File Submissions
- **FDA Process Validation** for all GMP Manufacturing Systems
- Complete Testing of all Finished Manufactured Lots
- On-site Quality Control Labs Operating 24/7
- Robust Preventive Maintenance Program
- State-of-the-art Instrumentation
- FDA Registered & Inspected
- Raw Materials:
  - Qualified and Inspected Sources
  - 100% Authentic Traceability
  - Complete Testing



### Comprehensive Quality & Regulatory Program

#### Quality Assurance



- Validation of all GMP Manufacturing Systems
- Rigorous Preventive Maintenance Program
- Qualification of all Equipment
- Stringent Cleaning Protocols
- Environmental Monitoring
- Change Control Process
- Equipment IQ-OQ-PQ
- Document Control







#### **Regulatory Control & Support**

- Creation and Submission of Drug Master Files for APIs and Excipients
- Creation and Control of all Critical Documentation
- Management of all External Audits and Certifications

#### **Quality Control**



- Validation and Verification of all Test Methods
- Qualification of all Instrumentation including ICP-MS, GC-MS, HPLC, UV/Vis, TOC, Ion Chromatographer, Conductivity Meter, Microcount UATR, Polarimeter, Karl-Fisher Titrator & more





#### **GMP Support Package**

GMP Support Package for all ICH-Q7 Level Products

#### **Analytical Support**

- Analytical Method Validation
- · Transfer of Analytical Methods
- Custom Analytical Methods and Specifications
- Bioburden and Endotoxin Testing
- Complete Impurity Profile
- Elemental Impurities
- Residual Solvents





#### **Development Support**

- Stability Study
- Custom GMP Services as needed
- Custom Labeling and Packaging
- Manufacture of API Registration Batches
- Drug Master File submission
- · Letter of Authorization
- · Efficient Development Timeline
- · High-touch management of your project

#### Ongoing Support - Post FDA Approval

- Commercial Manufacturing of your API
- On Site Audits
- Annual Product Review
- · Management of Change
- Post Submission Change Notification
- · Full support through the life of your product

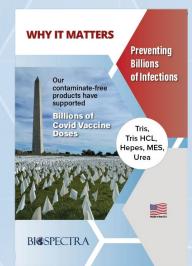


## WHY IT

### **MATTERS**

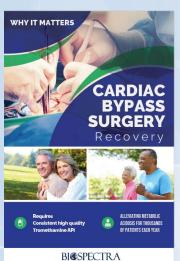
Our Internal Marketing Campaign

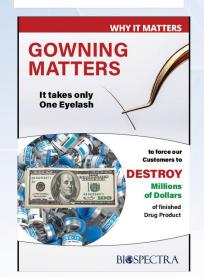










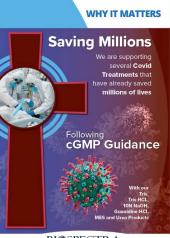




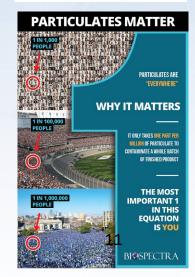








**BI** SPECTRA



## Our Focus

#### **Premium Pharmaceutical Ingredients**

#### 1. Solving Key Ingredient Needs

- a) Launching New Commercial Products
- b) Full cGMP Product Development
- c) Synthesis, Purification & Technical Support



#### 2. Upgrading Your Supply Chain

Facilitating the move to higher levels of:

- a) Quality
- b) Security
- c) Regulatory Compliance

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#### 3. Commercial Volumes

- a) Scalable
- b) Sustainable
- c) Supported through your Product Lifecycle



#### **CRITICAL INGREDIENT ISSUES?**

Purity?

Security?

Source?

Scale?

Synthesis?

**Specifications?** 

**Compliance Standard?** 



#### **Critical Manufacturing & Ingredient Issues:**

Inconsistencies from lot to lot / Insufficient purity levels / Contamination / Need for "real" GMP mfg. / Non-dedicated facilities / Incomplete testing & Documentation deficiencies / Absence of true traceability / High Microbial & Endotoxin levels / Recalled or scrap product / Need for custom specifications / Need for higher levels of quality and compliance

#### **Supply Chain Security Issues:**

Availability / Reliability & trustworthiness / Distance / Safety stock / Manufacturing interruptions / Authentic chain of custody

#### **Regulatory Issues:**

IPEC, ICH, GMP, FDA, EMA Compliance issues / Need for global specifications / Need for true validated manufacturing processes / Requirement for a higher compliant raw material

## Mitigation Experts

**Premium Pharmaceutical Ingredients** 

## SOLUTION

- True GMP Process
- Actual Purification
- Dedicated Facilities
- Base Synthesis of raw materials
- US Manufactured GMP Products
- True Quality-Based Manufacturing
- Total Quality Program: QC / QA / Regulatory
- 100% Reliable Traceability of all raw materials
- Proven record of adherence to GMP,
   IPEC, ICH Guidelines



BioSpectra represents consistent high quality, uniformly manufactured pharmaceutical ingredients.

Always synthesized, purified or compounded under true GMP standards.

Always manufactured at the appropriate specifications and compliance levels for the intended use in the final drug product.

## **Business Model**

#### Exclusive to Bio Pharma and Traditional Pharma

#### Stroudsburg PA



**GMP** Buffers

#### Bangor PA



GMP EXCIPIENTS & PROCESS
CHEMICALS

#### Mid-Large Comm. Volumes

#### **EXAMPLE**

**Large Commercial Volumes** 

TRIS, TRIS HCl, MOPS,
Guanidine HCl

#### **EXAMPLE**

Trehalose Dihydrate, Galactose, Na- Decanoate, Uridine, MES, HEPES, 10N NaOH, Buffer Solutions

#### Rensselaer NY



SMALL MOLECULE, GMP API's & EXCIPIENTS

#### **Small Commercial Volumes**

#### **EXAMPLE**

Uracil, Dextran Sulfate 8000, L-Hist., Mono-Mono, Hydrolyzed PVA API's: Uridine & Cytidine

BioSpectra sells buffers, denaturants and other products into large molecule BioPharma, but also manufactures GMP process chemicals, Excipients and API products for traditional, synthetically derived, small molecule, Pharma.

## What We Do

**Synthesis** 

API's

Small Molecule NCE's

Chlorinated Amino Acids **Purification** 

**Bio Buffers** 

Carbohydrates

Fine Chemicals GMP Solutions

Contract GMP Manufacturing

> Parenteral Ingredients

Excipients

### What We Do





## Product Grades & Compliance Levels

#### **Premium Pharmaceutical Ingredients**

Bio Ultra & Bio Ultra w/ BET (LBLE)\*
Bio Pharma & Bio Pharma w/ BET (LBLE)\*
Bio Excipient & Bio Excipient w/ BET (LBLE)\*
Bio Active & Bio Active w/ BET (LBLE)\*

\*Note: LBLE = Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

- cGMP (US-GMP)
- IPEC (International GMP)
- FDA Registration / Inspection
- Internal Controls and Systems
- ICH Q7 & other applicable USP & ICH standards



## Facility Profile



#### **Overall**

Facilities: 343,000 sq. ft. 52+ Acres 5 Campuses in PA and NY Staff: 300+ Employees More Info: www.biospectra.us



#### **Biological Buffer Manufacturing**

Bulk Manufacturing Facility, Quality Assurance & Control Address: 1474 Rockdale Lane, Stroudsburg, PA 18360 Staff: 50+ Employees | Site: 25,000+sg. ft. on 3+ Acres



Bulk Manufacturing Facility & Head Corporate Offices:
Administration, Regulatory Affairs, Quality Assurance & Control
Address: 100 Majestic Way, Bangor, PA 18013
Staff: 125+ Employees | Site: 150,000+sq. ft. on 37+ Acres



**Supply Chain Center** 

Shipping and Receiving & Security HQ
Address: 3<sup>rd</sup> Street, Stroudsburg, PA 18360
Staff: 20+ Employees | Site: 60,000+sq. ft. on 2+ Acres



**Bio Development Inc** 

R&D Kilo-Scale GMP Manufacturing Address: 11 University Place, Rensselaer, NY 1214 Staff: Growingl Site: 10,000+sq. ft.

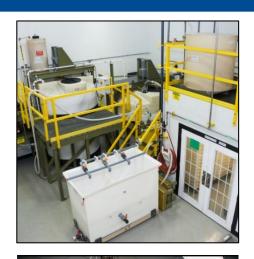


**Corporate Services Center** 

Commercial, IT, HR, Finance & Training Center Address: 1349 Jacobsburg Road, Wind Gap, PA 18091 Staff: 30+ Employees | Site: 25,000+sq. ft. on 2+ Acres

## Key Equipment & Manufacturing Scale

#### **Premium Pharmaceutical Ingredients**



- More than 24 GMP Manufacturing Suites with compliance levels ranging from IPEC to ICH Q7
- More than 30 Glass, 316-Stainless Steel and Composite Reactors
- Environmentally controlled Packaging Rooms
- Quality Control Labs with industry leading instrumentation



Drying Systems: Spray / Fluid Bed / Rotary / Tray



Scale & Capacity



- Reactors: Solvent & Alcohol / Corrosive Resistant Glass Lined / Stainless Steel
- Reactor Scale: 20L to 6,000L
- Solutions Batch Scale: 800L to 14,000L
- Dry Batch Scale: 1 kg to 20,000 kg
- Overall Operational Capacity: Thousands of Metric Tons per Year

## cGMP Warehouse Complex

51 North 3rd Street Stroudsburg, PA 18360















# PURIFIED - cGMP BIOLOGICAL BUFFERS

**Exclusively Manufactured in the USA** 



TROMETHAMINE, TRIS HCI,
GUANIDINE HCI, UREA,
HEPES, MES, MOPS



- Bulk Solutions
- Multi-Compendial
- Pharma GMP Process
- Excipient & API Grades
- Low Bioburden / Endotoxin

STRINGENT QUALITY PROGRAM
FDA Registered and Inspected / US GMP / IPEC / ICH Q7 Guidelines



## GMP BULK SOLUTIONS

**Exclusively Manufactured in the USA** 



NaOH 10N, 5N, 2N, 1N & 0.1N Custom Buffer Blends Guanidine HCI 6M IPA/HCI 6M NaCI 5M Urea 6M



- Made w/ WFI
- Sterile Filtered
- Class 7 Mfg. Suites
- Sterile Single-use Pkg
- Custom Compendial Specs

STRINGENT QUALITY PROGRAM

FDA Registered and Inspected / US GMP / IPEC / ICH Q7 Guidelines



# CONTRACT cGMP MANUFACTURING

ACTIVES | EXCIPIENTS | PROCESS CHEMICALS



Synthesis
Compounding
Purification

Aqueous Solvent Alcohol





- Small Molecules
- Custom Solutions
- Functional Excipients
- Scale Up Bench to Bulk
- **Small & Large Commercial Qty's**

STRINGENT QUALITY PROGRAM
FDA Registered and Inspected / US GMP / IPEC / ICH Q7 Guidelines



## ICH Q7 PARENTERAL INGREDIENTS

LOW BIOBURDEN - LOW ENDOTOXIN - HIGH PURITY



Rigorous Quality System
Validated GMP Process
State-of-the-art facility



- APIs
- BUFFERS
- EXCIPIENTS
- AMINO ACIDS
- CARBOHYDRATES
  - **SMALL MOLECULES**

STRINGENT QUALITY PROGRAM
FDA Registered and Inspected / US GMP / ICH Q7



# Functional Small Molecules Kilo-Scale / cGMP

Located in Rensselaer NY & Bangor PA, USA



**Eight Multipurpose Suites** 

Wide Range of Synthesis

5-15 Kg Batch Sizes



- Orphan Drug Support
- Functional Small Molecules
- Parenteral/Transdermal/Oral Application

STRINGENT QUALITY PROGRAM
FDA Registered and inspected / US GMP / ICH Q7

## Summary List of Products

L-Arginine HCl – GMP, USP, EP, JP, Pharma Process Grade

BIS-TRIS – GMP, LBLE, Bio Excipient Grade

BIS-TRIS HCl – GMP, LBLE, Bio Excipient Grade

Cholesterol - Synthetic, Parenteral Excipient Grade

Cysteamine Hydrochloride - API Grade

L-Cystine Dihydrochloride – GMP, Pharma Process Grade

<u>Cytidine</u> – API Grade

Dextran 70,000 - GMP, Bio Excipient Grade

Dextran Sulfate Sodium 8000 MW - GMP, Pharma Process Grade

Galactose - GMP, Excipient Grade- Low Bioburden, Low Endotoxin (LBLE), Low Elemental Impurities (LEI), Multicompendial

Glycerine, Synthetic Parenteral - USP/EP/JP/ChP – cGMP, excipient, Multicompendial

L-Glutamine – GMP, LBLE, Bio Excipient Grade

Guanidine HCl – GMP, Pharma Process and Excipient Grades

<u>Guanidine HCl, 6M Solution</u> – GMP Pharma Process and Excipient Grades

Guanidine Thiocyanate - GMP, Pharma Process Grade

HEPES Free Acid – GMP, Pharma Process, and Excipient Grades

HCl in IPA (6N) - GMP, Pharma Process Grade

L-Histidine – GMP, Parenteral Excipient Grade

L-Histidine Monohydrochloride, Monohydrate – GMP, LBLE, EP, JP, Bio Excipient Grade

2MEA (Cysteamine Hydrochloride) - GMP, Excipient Grade-Low Bioburden, Low Endotoxin (LBLE)

MES Monohydrate – GMP, Pharma Process, and Excipient Grades

MOPS Free Acid – GMP, Pharma Process and Excipient Grades

Potassium Bromide (KBr) - GMP, API Grade

Sodium Chloride 5N - GMP, Sterile Filtered, made with WFI, BPC, Excipient Grade

<u>Sodium Decanoate</u> – GMP, Functional Excipient for Parenteral Applications

Sodium Hydroxide 10N – GMP, <5 ppm Cl, made with WFI, BET Tested

Sodium Hydroxide, 25%, 5N, 2N, 1N, 0.5N, 0.1N - GMP, made with WFI, Low Chloride

<u>Trehalose Di Hydrate</u> – GMP, Excipient Grade– Low Bioburden, Low Endotoxin (LBLE), Low Elemental Impurities (LEI) - Multicompendial

Trehalose Di Hydrate – Synthetic, API Grade

<u>Tris HCl</u> – GMP, Pharma Process, Excipient, and LBLE Grades

<u>Tris/Tromethamine</u> – GMP, Pharma Process, Excipient, LBLE and API Grades -Multicompendial

Uracil - GMP, Pharma Process Grade

Uracil – API Grade

<u>Urea, 6M Solution</u> – GMP, Bio Excipient Grade – made with WFI

<u>Uridine</u> – GMP, Bio Excipient Grade

Uridine – API Grade

Water for Injection (WFI) – GMP, Multicompendial, USP, EP, JP

In Development / Coming Soon

## **Product Overview**

## **BIOSPECTRA**

Premium Pharmaceutical Ingredients



### Current & Future Programs and Projects

#### Nitrogen Based Electron Pulse Spray Dry Technology

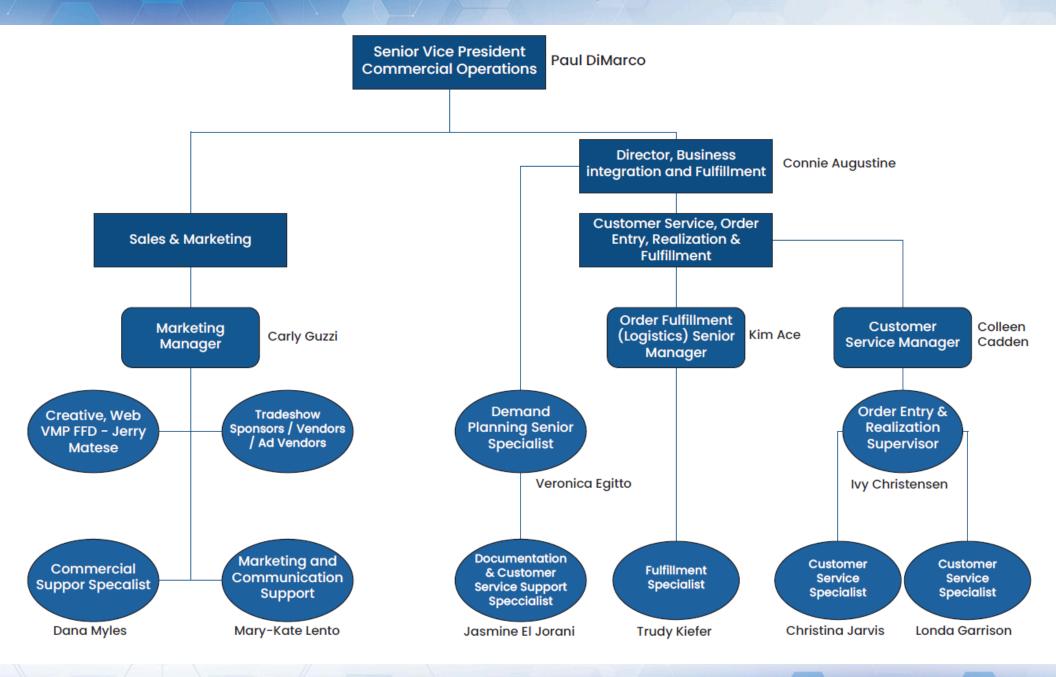


- ✓ Expanding Spray Dry
   Technology for various
   buffers and other Chlorinated
   products
- ✓ Offers efficiency in production
- ✓ Lowers exposure during drying process
- ✓ Reduced human "touch points"
- ✓ Creates less dense, more free-flowing material

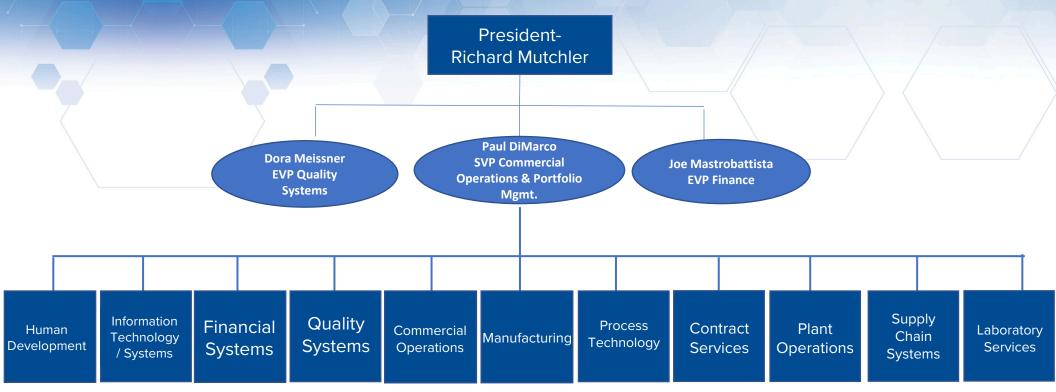
### Current & Future Programs and Projects Continued

- 1. Small Molecule R&D and Synthetic Capabilities:
  - a. Rensselaer NY
  - b. Mumbai India
- 2. Expanded Advanced Instrumental Capabilities: Elemental Analysis (ICP-MS and ICP-OES) and Particle Identification (Electron Microscopy)
- 3. Expanded GMP Carbohydrate Polymer Line (Dextrans)
- 4. Supply Chain Security: Raw material synthetic platform expansion for pilot and commercial scale (Sarigam, Gujarat, India)
- 5. Expanded automated packaging facility and wet labs (Monroe Plaza Complex, Stroudsburg PA)
- 6. Sustainability Program three year program to address key sustainability issues
- 7. Virtual Market Place and future e-commerce site

### **Commercial Operations**

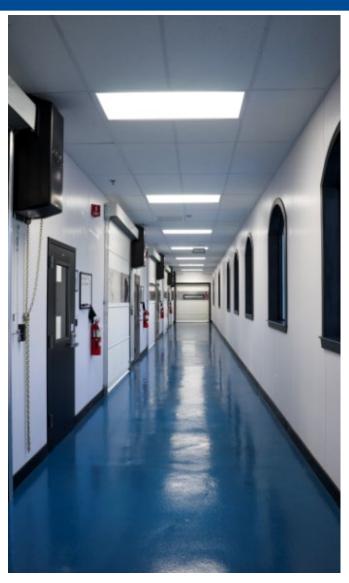


### Corporate Organizational Chart



## Final Word

#### We Seek to Service...



#### **Customers who are seeing:**

- Increased security of supply
- A company with a strong growth model to support future commercial demands
- A company with a proven track record of commitment to the Pharmaceutical Industry
- A company focused on customer needs
- A flexible, transparent and responsive supplier
- A company committed to Sustainable Solutions
- A company investing in future technology

#### **Customers who:**

- Have critical ingredient issues that fall within our scope of chemistry, capabilities and capacity
- Need higher-purity, higher-compliance Pharma ingredients or cGMP process fine chemicals Ingredients
- Value full cGMP synthesized and/or purified products